

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **18 MAY 2005 (18.05.2005)**

Applicant's or agent's file reference
MK-158/A/PCT

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/KR2005/000209

International filing date (day/month/year)
26 JANUARY 2005 (26.01.2005)

Priority date(day/month/year)
27 JANUARY 2004 (27.01.2004)

International Patent Classification (IPC) or both national classification and IPC
IPC7 A61K 31/403, A61P 35/00

Applicant

ANYGEN CO., LTD. et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/KR



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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/KR2005/000209

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/KR2005/000209

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|--------|-------|-----|
| Novelty (N) | Claims | | YES |
| | Claims | 1 - 3 | NO |
| Inventive step (IS) | Claims | | YES |
| | Claims | 1 - 3 | NO |
| Industrial applicability (IA) | Claims | 1 - 3 | YES |
| | Claims | | NO |

2. Citations and explanations :

The following documents are referred to in this report:

D1: WO 00/61555 A1 (19 Oct. 2000)

D2: WO 01/37819 A2 (31 May 2001)

D3: WO 99/62503 A2 (09 Dec. 1999)

1. Novelty

Claims 1-3 of the present invention relate to indirubin derivatives of formula (I)~(VII) and anticancer compositions comprising the same.

D1 discloses the compound of formula (V) in example 15 and the compound of formula (VII) in example 28, which can be used for the manufacture of a medicament for the treatment of solid cancers.

Thus, the novelty of claims 1-3 can be denied by D1 [Article 33(2) PCT].

2. Inventive Step

Since the novelty of claims 1-3 cannot be acknowledged over D1, the inventive step of them cannot be acknowledged, either.

In addition, the indirubin derivatives of formula (I)~(VII) are also expected from D2 or D3 by properly combining the substituents in the Markush forms, and the anticancer effects of formula (I)~(VII) in the present invention do not seem to be surprising when one consider the variability of anticancer effects among the indirubin derivatives disclosed in D2 and D3.

Therefore, the inventive step of claims 1-3 can also be denied by D2 or D3 [Article 33(3) PCT].

3. Industrial Applicability

The subject-matter of claims 1-3 appears to be industrially applicable [Article 33(4) PCT].